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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------------------------------------------------------|-------------|----------------------|----------------------------|------------------|
| 09/752,939 | 12/29/2000 | Bruce L. Gibbins | KCX-1743 (64665657US02) | 9231 |
| 22827 | 7590 | 10/18/2011 | EXAMINER | |
| DORITY & MANNING, P.A. POST OFFICE BOX 1449 GREENVILLE, SC 29602-1449 | | | GHALI, ISIS A D | |
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| | | | 1611 | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/752,939 | GIBBINS ET AL. | |
| | Examiner | Art Unit | |
| | Isis Ghali | 1611 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1,2,4,6,8,21,23-28,31-35,38-43,45-59 and 61-72 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1,2,4,6,8,21,23-28,31-35,38-43,45-59 and 61-72 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>08/10/2011</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

The receipt is acknowledged of applicants' amendment and declaration under 37 C.F.R. 1.131, both filed 08/09/2011 and IDS filed 08/10/2011.

Claims 1, 2, 4, 6, 8, 21, 23-28, 31-35, 38-43, 45-59, 61-72 are pending and included in the prosecution.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 2, 4, 6, 8, 21, 23-28, 31-35, 38-43, 45-59, 61-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ladin (US 5,792,090, of record) in view of Geistlich (WO 90/03810, IDS filed 08/10/2011) and Murdock (US 2002/0042587, of record).

Applicant's claims

Claim 1 is directed to an oxygen-delivery wound treatment, comprising a biocompatible, single unit matrix for delivering oxygen, comprising a) a swellable, cross-linked polyacrylamide polymer network, b) deliverable oxygen in elastic closed cells that are permeable to gas within the cross-linked polyacrylamide polymer network wherein after the polyacrylamide polymer network is cross-linked, the closed cell are formed by oxygen produced by reacting the catalyst and a second reactant, and wherein with use of the matrix, oxygen is delivered from the closed cells.

Claim 38 is directed to an oxygen delivery wound treatment device, comprising a biocompatible, single unit matrix for delivering oxygen, comprising; a) a swellable, cross-linked polyacrylamide polymer network, b) deliverable oxygen in elastic closed cells that are permeable to gas and within the cross-linked polyacrylamide polymer network a second reactant and a catalyst reaction occurred, and c) at least one active agent.

Claim 39 is directed to a biocompatible, single unit cross-linked polyacrylamide matrix, comprising a swellable, cross-linked polyacrylamide polymer network, and deliverable oxygen in elastic closed cells that are permeable to gas and within the cross-linked polyacrylamide polymer network at sites where a reaction of a catalyst and a second reactant occurred.

The present claims 1, 38 and 39 recite a product comprises matrix of closed cell foam of cross-linked polyacrylamide polymer containing oxygen produced by reaction of catalyst and reactant. The limitation of oxygen delivery is directed to intended use that impart patentability to composition claims. The limitation when oxygen is produced in the crosslinked polyacrylamide network is directed to process of making the product. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695,698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Determining the scope and contents of the prior art (MPEP § 2141.01)

Ladin teaches wound dressing that supply oxygen to the wound for optimal healing and minimization of infection because the wound causes diffusion limited access and limits the oxygen supply to the wound (abstract; col.2, lines 28-31). The dressing comprises polymeric foam comprising elements that react to generate oxygen that are hydrogen peroxide and catalyst such as magnesium dioxide or enzymes (col.6, lines 6-26). The catalyst is contained in the foam which absorbs hydrogen peroxide into the foam to produce oxygen (col.7, lines 48-55). The foam comprises guar gum or polyacrylamide, and further comprises collagen, i.e. non-gellable foam (col.4, lines 39-42; col.12, line 7). Ladin teaches that the decomposition catalyst may be contained within a foam that can be open-celled foam or other foams disclosed by U.S. Pat. Nos. 4,193,813 or 4,703,108 (col.7, lines 47-57). These patents do not teach open-celled foam, i.e. teach closed cell foam.

Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art (MPEP § 2141.012)

Although Ladin teaches polyacrylamide foam, however, the reference does not explicitly teach crosslinked polyacrylamide or closed cell foam in particular.

Geistlich teaches wound healing composition in its preferred form comprises cross-linked polyacrylamide and gellable substance. The composition used in the form of dressing for direct application to the wound for delayed release of wound healing

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agents. The dressing has the advantage of very good compatibility with the wound and ease of removal from the wound without damage to the growing tissue. (See abstract; page 3, last paragraph; page 4).

Murdock teaches polymeric cross-linked foam reservoir comprising cellulose derivatives and active agent including anti-infective agents and growth factors (abstract; paragraphs 0035, 0049, 0050). The foam reservoir is closed cell foam wherein the closed cells can be produced chemically and contains gasses including oxygen (paragraph 0036). The closed cell foam provides thin matrix with high surface area with respect to the matrix (paragraphs 0011, 0016).

Resolving the level of ordinary skill in the pertinent art (MPEP § 2141.012)

Therefore, at the time of the invention it was known to treat wound using polyacrylamide foam matrix containing oxygen produced by chemical reaction between peroxide and catalyst as taught by Ladin, and replace polyacrylamide by crosslinked polyacrylamide taught by Geistlich. One would have been motivated to do so because Geistlich teaches that cross-linked polyacrylamide wound dressing has the advantage of very good compatibility with the wound and ease of removal from the wound without damage to the growing tissue. One would reasonably expect formulating cross-linked polyacrylamide foam matrix containing oxygen that is produced chemically by the reaction of peroxide and catalyst wherein dressing is compatible with the wound and easily removed without damaging the underneath growing tissue.

Further, it would have been obvious to one having ordinary skill in the art at the art at the time of the invention to use the closed cell foam taught by Murdock in the foam matrix taught by the combination of Ladin and Geistlich because Murdock teaches that closed cell crosslinked polymer foam matrix is thin and has high surface area with respect to the matrix and oxygen can be delivered chemically in foam. One would reasonably expect formulating cross-linked polyacrylamide closed cell foam matrix containing oxygen that is produced by the reaction of peroxide and catalyst wherein the matrix is thin, yet can deliver therapeutic agents.

It is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. 103 (a) because the invention as a whole is taught by the combined teaching of the cited references.

Response to Arguments

5. Applicant's arguments filed 08/09/2011 have been fully considered but they are not persuasive.

Applicants' argument concerning Gibbins's reference is moot in view of the new ground of rejection necessitated by the IDS filed 08/10/2011.

Applicants argue that Murdock teaches cross-linked polymeric closed cell foam but does not mention polyacrylamide.

In response to this argument, it is argued that cross-linked polyacrylamide is taught by the currently cited reference Geistlich. One cannot show nonobviousness by attacking the references individually where the rejections are based on combination of references. *See In re Keller*, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 231 USPQ 375 (Fed. Cir. 1986).

Applicants argue that Ladin and Murdock do not teach the present invention. The references teach away from each other because Ladin teaches open cell foam, and Murdock teaches closed cell foam. Thus, there would be no motivation for a person of skill to combine the two references to make the claimed invention with a reasonable expectation of success. Further, modification of the open cell foam as taught by Ladin to create closed cell foam as taught in the instant application would render Ladin unsatisfactory for its intended purpose.

In response to this argument, it is argued that Ladin teaches open cell foam as an example and not as exclusion of other types of foam. At column 7, lines 47-57, Ladin teaches "The decomposition catalyst may be contained within a foam. For example, an open-celled polyurethane foam may be prepared by reacting an isocyanate component

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with a polyol component, one or both of the latter containing ground manganese dioxide. The oxygen source, i.e. hydrogen peroxide, may then be absorbed into the foam whereupon it will be decomposed to produce oxygen. Likewise, other foams, including those of biologically derived materials, such as collagen sponge prepared by the method of U.S. Pat. Nos. 4,193,813 or 4,703,108 may be used". The alternative foams used by Ladin and cited by the above references are not open cell foam. It had been decided by Courts that the indiscriminate selection of "some" from among "many" is considered prima facie obvious. *In re Lemin*, 141 USPQ 814 (1964); *National Distillers and Chem. Corp. V. Brenner*, 156 USPQ 163. Further, the selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). "Reading a list and selecting a known compound to meet known requirements is no more ingenious than selecting the last piece to put in the last opening in a jig-saw puzzle." 325 U.S. at 335, 65 USPQ at 301. See also *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960); *Ryco, Inc. v. Ag-Bag Corp.*, 857 F.2d 1418, 8 USPQ2d 1323 (Fed. Cir. 1988). Ladin suggests any foam, which can be either closed cell or open cell, and Murdock teaches closed cell foam. Therefore, Ladin and Murdock do not teach away from each other because both are in the field of applicant's endeavor, and reasonably pertinent to the particular problem with which the applicant was concerned, which is wound dressing and treatment. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from

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following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant. The degree of teaching away will of course depend on the particular facts; in general, a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant." *In re Gurley*, 27 F.3d 551,553 (Fed. Cir. 1994). This is not the case here because one having ordinary skill in the art would not be discouraged from using closed cell foam of Murdock in view of the teaching of Ladin that permits foams other than open celled. The combination of the references is proper and teaches the present invention as a whole.

Applicants argue that the Office Action has failed to make a prima facie case of obviousness because (i) there is no suggestion or motivation, either in the references themselves or in the knowledge of a person of ordinary skill in the art, to modify the references or combine the references' teachings; (ii) there is no reasonable expectation of success; and (iii) the prior art references alone or in combination do not teach or suggest all of the claim limitations.

In response to the above argument, the examiner believes that the prima facie case of obviousness has been established because:

(i) There is motivation to combine the references, and motivation is in the references themselves, as set forth in this office action. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would

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otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985)

(ii) Reasonable expectation to achieve the present invention exists. Combination of references will provide cross-linked polyacrylamide closed cell foam matrix containing oxygen that is produced by the reaction of peroxide and catalyst, as applicants have done. It is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

(iii) The combination of the cited prior art teaches the present invention as a whole. In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter as a whole as defined by the claims would have been prima facie obvious within the meaning of 35 U.S.C. 103 (a).

Response to Amendment

6. The declaration filed on 08/09/2011 under 37 CFR 1.131 has been considered but is ineffective to overcome the Gibbins's reference (US 5,928,174) for the following reasons:

a) The declaration is only signed by one inventor, and not by all the joint inventors of the present application.

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b) Although the signing inventor is swearing behind US patent, however, it is not evident that the work of the present invention was done in US, NAFTA or WTO. The evidence submitted is insufficient to establish a reduction to practice of the invention in this country or a NAFTA or WTO member country prior to the effective date of the US 5,928,174 reference. The declaration should include a statement that the invention was made in US, NAFTA or WFO, and this statement is missing from the declaration. See MPEP, section 715 [R-3] where it is stated that:

“Under 37 CFR 1.131(a) as amended, which provides for the establishment of a date of completion of the invention in a NAFTA or WTO member country, as well as in the United States, an applicant can establish a date of completion in a NAFTA member country on or after December 8, 1993, the effective date of section 331 of Public Law 103-182, the North American Free Trade Agreement Act, and can establish a date of completion in a WTO member country other than a NAFTA member country on or after January 1, 1996, the effective date of section 531 of Public Law 103-465, the Uruguay Round Agreements Act (URAA). Acts occurring prior to the effective dates of NAFTA or URAA may be relied upon to show completion of the invention; however, a date of completion of the invention may not be established under 37 CFR 1.131 before December 8, 1993 in a NAFTA country or before January 1, 1996 in a WTO country other than a NAFTA country. If a country joined the WTO after January 1, 1996, the effective date for proving inventive activity in that country for the purpose of 35 U.S.C. 104 and 37 CFR 1.131 is the date the country becomes a member of the WTO. See

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MPEP § 201.13 for a list that includes WTO member countries (the notation "W o" indicates the country became a WTO member after January 1, 1996)."

c) The date applicant swearing behind "at least as early as July 26, 1999", is not sufficient because the reference has effective filing date November 14, 1997. In any event, no evidence of any reduction to practice is provided.

d) Additionally, the declaration is insufficient because the declaration does not show what was conceived before the reference date. While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See *Mergenthaler v. Scudder*, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir. 1897). The present claimed invention is not identical to the invention conceived prior to the effective filing date of the US 5,928,174 reference.

However, applicants' statement of common ownership was sufficient to overcome the rejection of the claims over Gibbins's reference.

Conclusion

7. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 08/10/2011 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS**

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MADE FINAL. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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